**LIST OF APPROVALS/ RENEWALS, CHECK LIST OF DOCUMENTS REQUIRED, TIMELINE FOR APPROVAL & APPLICABLE FEES UNDER STATE DRUG CONTROL**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SL NO** | **APPROVALS/ RENEWALS** | **CATEGORY** | **LIST OF DOCUMENTS TO BE SUBMITTED** | **TIMELINES FOR APPROVAL** | **APPLICABLE FEES** |
| 1 | Application for grant of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X **Form 19** and additional information (wholesale)Drugs Licence in **Form 20-B &21-B** | Pre-Establishment | 1. A. Applicant or person incharge of the premises should be (a) registered pharmacist or (b) Experienced in dealing with drugs(Wholesale trade) for Four (4) years in case of Matriculation or equivalent examination or experienced in dealing with drugs(wholesale trade) for 1(One) year in case of holding a degree of a recognized university.1. B. Appoint & joining letter of the person in charge with 2 passport size photograph if applicable.**ANNEXURE-I(A,B & C).**2. NOC for Stockist ship with valid GMP certificate of a modern medicine Mfg. unit.3. Education qualification certificate.4. Proof of availability of cold storage facility.5. Approved layout premises (10 sq.m-15 sq.m).6. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.7. Proof of constitution of the firm.8. Proof of Residential address and Photo identity of the applicant and person incharge. 9. Applicant-Proprietor /Partners.10. Memorandum of article if applicable.  | 45 days |  Treasury Challan of Rs.3000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 2 | Application for grant of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X **Form 19** and additional information (retail) Drugs Licence in **Form of 20 & 21** | Pre- Establishment | 1. Up to date registration of renewal certificate of the registered pharmacist (under section 32(2) of Assam Pharmacy Council) 2. Appointment letter and joining report of the pharmacist. 3. Consent letter of the pharmacist with 2 copies of passport size photograph.4. Court Affidavit of registered pharmacist & the applicant.(Records of previous engagement of Pharmacist is to be attached). **ANNEXURE-II (Sl. No. 3,4 &5).**5. Educational qualification certificate of applicant & person in charge.6. Proof of availability of cold storage facility.7. Approved layout premises (10 sq.m-15 sq.m).8. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.9. Proof of constitution of the firm.10. Proof of Residential address & photo identity of the applicant. | 45 days | Treasury Challan of Rs.3000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 3 | Application for grant of a licence to sell, stock, exhibit or offer for sale, or distribute drugs specified in Schedule X **Form 19 C** and additional 0information (wholesale) Licence **Form-20 G.** | Pre Establishment | 1. A. Applicant or person in charge of the premises should be (a) registered pharmacist or (b) Experienced in dealing with drugs(Wholesale trade) for Four (4) years in case of Matriculation or equivalent examination or experienced in dealing with drugs(wholesale trade) for 1(One) year in case of holding a degree of a recognized university.1. B. Appoint & joining letter of the person incharge with 2 passport size photograph if applicable.**ANNEXURE-I(A, B & C).**2. NOC for Stockiestship with valid GMP certificate of a modern medicine Mfg. unit.3. Education qualification certificate.4. Proof of availability of cold storage facility.5. Approved layout premises (10 sq.m-15 sq.m).6. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.7. Proof of constitution of the firm.8. Proof of Residential address and Photo identity of the applicant and person in charge. 9. Memorandum of article if applicable.  | 45 days | Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 4 | Application for grant of a licence to sell, stock, exhibit or offer for sale, or distribute drugs specified in Schedule X **Form 19 C** and additional information (retail)Licence **Form-20-F** | Pre Establishment | 1. Up to date registration of renewal certificate of the registered pharmacist (under section 32(2) of Assam Pharmacy Council) 2. Appointment letter and joining report of the pharmacist. 3. Consent letter of the pharmacist with 2 copies of passport size photograph.4. Court Affidavit of registered pharmacist & the applicant.(Records of previous engagement of Pharmacist is to be attached). **ANNEXURE-II (Sl. No. 3,4 &5).**5. Educational qualification certificate of applicant & person in charge.6. Proof of availability of cold storage facility.7. Approved layout premises (10 sq.m-15 sq.m).8. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.9. Proof of constitution of the firm.10. Proof of Residential address & photo identity of the applicant. | 45 days | Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 5 | Application for grant of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by retail by dealers who do not engage the service of a qualified person **Form 19A** and additional information ( Restricted General store) | **Temporarily stopped by the government** | 1. Experience Certificate in Trade with 4 years and hold a degree of a recognised university with 1 year experience in dealing with drugs.2. Education qualification certificate.3. Proof of availability of cold storage facility.4. Approved layout premises (10 sq.m-15 sq.m).5. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.6. Proof of constitution of the firm.7. Residence address of the appliances, etc. | 45 days | .Treasury Challan of Rs.1000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 6 | Application for grant of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by wholesaler by dealers who do not engage the service of a qualified person **Form 19A** and additional information ( Restricted Seller) Drugs Licence in **Form** of **20-A & 21-A.** | **Temporarily stopped by the government** | 1. Experienced in dealing with drugs (Retail trade) with 4 years after having matriculation or equivalent examination or above. **ANNEXUR-III**2. Education qualification certificate.3. NOC from local authority (gaon panchayat).4. Approved layout premises (10 sq.m-15 sq.m).5. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.6. Proof of constitution of the firm.7. Proof of Residential address and photo identity of the applicant.  | 45 days | 1. Treasury Challan of Rs.1000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 7 | Application for grant or renewal of a licence to sell, stock or exhibit or offer for sale by wholesaler or distribute drugs from a motor vehicle, **Form 19 AA** and additional information. Licence **Form 20 BB & 21-B B.** | Pre Establishment | 1. Registration Certificate of the vehicle.2. Driving licence of the driver.3. Provision of cold storage facility.4. Experience certificate in the trade.5. Stockiest Certificate with valid GMP certificate6. Approved layout premises (10 sq.m-15 sq.m).7. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.8. Proof of constitution of the firm.9. Proof of Residential address and Photo identity of the applicant and person in charge. 10. Memorandum of article if applicable | 45 days | . Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 8 | Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines **Form 19 B** and additional information (Wholesaler) Licence **Form 20-D.** | Pre Establishment | 1. Applicant & person in charge should be (a) Registered Homoeopathic Practitioner or (b) Experienced in dealing Homoeopathic medicine for 4 years (wholesale trade) after matriculation or equivalent examination or (c) Experienced in dealing Homoeopathic medicine for 1 year after holding a degree of recognised university. **ANNEXURE-IV.** 2. NOC for stockiest ship with valid GMP certificate of a Homoeopathic medicine unit. 3. Education qualification certificate of the applicant or person in charged.4. Approved layout premises (10 sq.m-15 sq.m).5. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.6. Proof of constitution of the firm.7. Proof of Residential address and Photo identity of the applicant and person in charge.  | 45 days | Treasury Challan of Rs.260/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 9 | Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines **Form 19 B** and additional information (Retail)Licence **Form 20-C.** | Pre Establishment | 1. Applicant should be a registered Homoeopathic practitioner.2. Education qualification certificate.3. Approved layout premises (10 sq.m-15 sq.m).4. Proof of ownership of the premises/tenancy agreement with proof of the ownership of the owner of the premises.5. Proof of constitution of the firm.6. Proof of Residential address and Photo identity of the applicant and person incharge  | 45 days | Treasury Challan of Rs.260/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
|  | **LIST OF PRE OPERATION APPROVALS** |  |  |  |  |
| 10 | Application for grant of a licence to manufacture for sale for distribution of drugs other than those specified in [Schedule C, C(1) and X] **Form 24** and additional information. Licence **Form-25.** | Pre Operation | As per **ANNEXURE-V** | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 11 | Application for grant of a loan licence to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C(1) and X **Form 24 A. Licence Form 25-A.** | Pre Operation | 1. . True copy of a letter from the manufacturing concern whose manufacturing capacity is intended to be utilised by applicant2. True copy of a letter from the manufacturing concern that they agree to land the service of their expert staff, equipment and premise for manufacture of each attempt required by the applicant and that will analyse every batch of the finish product and maintain the register of the raw materials finish products and repose of the analysis separately on this behalf.3. Other documents to be submitted as per check list enclosed. **ANNEXURE-V**. | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 12 | Application for grant of a licence to repack for sale or distribution of drugs, being drugs other than those specified in Schedule C, C(1) excluding those specified in Schedule X **Form 24B** and additional information. Licence **Form 25-B.** | Pre Operation | As per **ANNEXURE-V** which over applicable for grant of a license to repack for sale and distribution. | 45 days | Treasury Challan of licence fee of Rs.500+inspection fee of 200 ( Rs 700/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 13 | Application for grant of a licence to manufacture for sale or distribution of homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensing holding licence in Form 20-C- **Form 24-**C and additional information. Licence **Form 25-C.** | Pre Operation | 1. Approved competent technical staff with Education Qualification Certificate.2. Approved layout of the premises.3. Quality control facilities.4. List of equipments.5. SOP, 6. Specimens of labels, cartons of the products proposed to be manufactured. 7.List of products to be manufactured8.Constitution of Firm | 45 days | Treasury Challan of licence fee of Rs.200+inspection fee of 100 ( Rs 300/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 14 | Application for grant of a licence to manufacture for sale or distribution of drugs, specified in Schedule X and not specified in Schedule C and C(1) **Form 24F** and additional information. Licence **Form 25-F.** | Pre Operation | As per **ANNEXURE-V** | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 15 | Application for grant of a licence to manufacture for sale or distribution of drugs, specified in Schedule C and C (1) excluding those specified in part XB and Schedule X **Form 27** and additional information. Licence **Form 28**  | Pre Operation | As per **ANNEXURE-V** | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 16 | Application for grant of a loan licence to manufacture for sale or distribution of drugs, specified in Schedule C and C (1) excluding those specified in part XB and Schedule X **Form 27 A** and additional information license **Form 28 A**  | Pre Operation | 1. . True copy of a letter from the manufacturing concern whose manufacturing capacity is intended to be utilised by applicant2. True copy of a letter from the manufacturing concern that they agree to land the service of their expert staff, equipment and premise for manufacture of each attempt required by the applicant and that will analyse every batch of the finish product and maintain the register of the raw materials finish products and repose of the analysis separately on this behalf.3. Other documents to be submitted as per check list enclosed. **ANNEXURE-V**. | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 17 | Application for grant of a licence to manufacture for sale or distribution of drugs, specified in Schedules C and C (1) and X, **Form 27 B** and additional information. Licence **Form 28-B.** | Pre Operation | As per **ANNEXURE-V**. | 60 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 18 | Application for grant of license for the operation of Blood Bank for processing of whole blood and/ or preparation of blood components. **Form 27 C** and additional information. Licence **Form 28-C.** | Pre Operation | . Documents should be submitted as per check list enclosed. **ANNEXURE-VI.**( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India)) | 120 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 19 | Application for grant of a license to manufacture for sale or for distribution of large volume Parenteral /Sera and Vaccines excluding those specified in Schedule X Form 27 D and additional information. Licence Form 28-D. | Pre Operation | Document to be submitted to the Licensing Authority for final approval as follows (**Check list enclosed**). **ANNEXURE-V**( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India)) | 120 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 20 | Application for grant of license to manufacture Blood products for sale or distribution **Form 27 E** and additional information. Licence **Form 28-E.** | Pre Operation | . Documents to be submitted as per Annexure-VI and schedule-F Part-XII B & /or XII C or XII D of Drugs & Cosmetics Act & Rules.( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India)) | 120 days | Treasury Challan of licence fee of Rs.6000+inspection fee of 1500 ( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 21 | Application for license to manufacture drugs for purpose of examination, test or analysis **Form 30** and additional information. Licence **Form 29.** | Pre Operation | Documents to be submitted as per check list enclosed **ANNEXURE-V which over applicable** | 30 days | Treasury Challan of licence fee of Rs 260/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 22 | Application for grant of a license to manufacture cosmetics of sale or for distribution **Form 31** and additional information. Licence **Form 32**.  | Pre Operation | Documents to be submitted as per check list enclosed **ANNEXURE-V.** | 45 days | Treasury Challan of licence fee of Rs.2500+inspection fee of 1000 ( Rs 3500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 23 | Application for grant of a loan license to manufacture cosmetics of sale or for distribution **Form 31 A** and additional information. Licence **Form 32 A.** | Pre Operation | 1. . True copy of a letter from the manufacturing concern whose manufacturing capacity is intended to be utilised by applicant2. True copy of a letter from the manufacturing concern that they agree to land the service of their expert staff, equipment and premise for manufacture of each attempt required by the applicant and that will analyse every batch of the finish product and maintain the register of the raw materials finish products and repose of the analysis separately on this behalf.3. Other documents to be submitted as per check list enclosed. **ANNEXURE-V**. | 45 days | Treasury Challan of licence fee of Rs.2500+inspection fee of 1000 ( Rs 3500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 24 | Application for grant of approval for carrying out tests drugs/cosmetics or raw materials used in the manufacture of drugs specified in Schedule C & C1 thereof on behalf of licenses for manufacture for sale of drugs/cosmetics **Form 36** and additional information Licence **Form 37.** | Pre Operation | As per **ANNEXURE-V** which over applicable | 45 days | Treasury Challan of inspection fee of Rs 6000/ in case of testing of drugs specified schedule C & C1 and Rs 1500/- in case of testing of drugs specified other than schedule C & C1, homoeopathic drugs and cosmetics under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
|  | **LIST OF THE POST COMMENCEMENT APPROVALS** |  |  |  |  |
| 25 | License No. 25,25 A,25F, 28, 28A, 28B, 28 D, 32 and 32 A | Post Commencement | 1. List of the additional item to be approved
2. Master Formula of additional item
3. Testing monogram of additional item
 | 20 days | Rs 300/- for each item has been credited to under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
|  | **RENEWAL/ RETURN** |  |  |  |  |
| 26 | Application for grant/ renewal of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X **Form 19** and additional information (wholesale)Renewal **Form 21-C.** | Renewal/ return | 1. Condition of licence under Rule 65 should be complied.2. Upto date renewal certificate in form 21-C or copy of the treasury challan of previous year if applicable. 3. Up to date rent agreement of the premises. | 30 days | 1. Treasury Challan of Rs.3000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 27 | Application for grant of a licence to sell, stock, exhibit or offer for sale, or distribute drugs other than those specified in Schedule X **Form 19** and additional information (retail) Renewal **Form 21C.** | Renewal/return | 1. Condition of licence under Rule 65 should be complied. 2. Up to date renewal certificate of pharmacist.3. Up to date court affidavit of pharmacist.4. Up to date rent agreement of premises.5. Up to date renewal certificate of D/L in from 21-C or Treasury challan copy if applicable. | 30 days | 1. Treasury Challan of Rs.3015/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 28 | Application for grant/ renewal of a licence to sell, stock, exhibit or offer for sale, or distribute drugs specified in Schedule X **Form 19C** and additional information (wholesale) Renewal **Form 21 C.** | Renewal / return | 1. Condition of licence under Rule 65 should be complied.2. Up to date renewal certificate or copy of treasury challan of previous year if applicable.3. Up to date rent agreement of the premises.  | 30 days | 1. Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 250 per month or part thereof. |
| 29 | Application for grant/ renewal of a licence to sell, stock, exhibit or offer for sale, or distribute drugs specified in Schedule X **Form 19C** and additional information (retail)Renewal **Form 21 C.** | Renewal/ return | 1. Condition of licence under Rule 65 should be complied. 2. Up to date renewal certificate of pharmacist.3. Up to date court affidavit of pharmacist.4. Up to date rent agreement of premises.5. Up to date renewal certificate of D/L in from 21-C or Treasury challan copy if applicable. | 30 days | 1. Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 250 per month or part thereof. |
| 30 | Application for grant of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by retail by dealers who do not engage the service of a qualified person **Form 19A** and additional information ( Restricted General store) | Renewal / return | . Condition of licence under Rule 65 should be complied | 30 days | 1. Treasury Challan of Rs.1000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 500 per month or part thereof. |
| 31 | Application for grant of a restricted licence to sell, stock or exhibit or offer for sale, or distribute drugs by wholesaler by dealers who do not engage the service of a qualified person **Form 19A** and additional information (Restricted Seller)Renewal certificate **Form-21-C.** | Renewal /return | 1. . Condition of licence under Rule 65 should be complied. 2. Up to date renewal certificate of D/L in form 21-C or copy of treasury challan of previous year if applicable.  | 30 days | 1. Treasury Challan of Rs.1000/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 500 per month or part thereof. |
| 32 | Application for grant or renewal of a licence to sell, stock or exhibit or offer for sale by wholesaler or distribute drugs from a motor vehicle, **Form 19 AA** and additional information. Renewal certificate in **Form-21-C-C.** | Renewal/return | 1. Condition of licence Form 20-BB & 21 BB should be complied. 2. Up to date renewal of driving licence.3. Up to date renewal certificate or copy of treasury challan of previous year if applicable. | 30 days | 1. Treasury Challan of Rs.500/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 200 per month or part thereof. |
| 33 | Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines **Form 19 B** and additional information (Wholesaler). Renewal **Form 20E.** | Renewal/ return | 1. Condition of licence Form 20-D should be complied.2. Up to date renewal certificate of D/L or copy of treasury challan of previous year if applicable.3. Upto date rent agreement of the premises.  | 30 days | 1. Treasury Challan of Rs.260/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 50 per month or part thereof. |
| 34 | Application for licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic Medicines **Form 19 B** and additional information (Retail). Renewal **Form 20E.** | Renewal/ return | 1. Condition of licence Form 20-C should be complied. 2. Up to date renewal certificate of D/L or copy of treasury challan of previous year if applicable.3. Up to date rent agreement of the premises.  | 30 days | 1. Treasury Challan of Rs.260/- under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 50 per month or part thereof. |
| 35 | Application for grant/ renewal of a licence to manufacture for sale for distribution of drugs other than those specified in [Schedule C, C(1) and X] **Form 24** and additional information. Renewal **Form 26.** | Renewal/ return | 1. Drug licence with list of products approved in the last licensing period.
2. Consolidated list
3. Production particulars for the last Licensing Period.
4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.
5. Original labels.
 | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 36 | Application for grant/ renewal of a loan licence to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C(1) and X **Form 24 A. Renewal Form 26-A.** | Renewal / return | 1. Drug licence with list of products approved in the last licensing period.
2. Consolidated list
3. Production particulars for the last Licensing Period.
4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.
5. Original labels.
 | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 37 | Application for grant/ renewal of a licence to repack for sale or distribution of drugs, being drugs other than those specified in Schedule C, C(1) excluding those specified in Schedule X **Form 24B** and additional information. Renewal **Form 26-B.** | Renewal / return | 1. Condition of licence under Form 25B should be complied. 2. Photo copy of original/ renewal D/L with list of product all ready approved.3. Consolidated list of product.4. Production particulars for the last Licensing period.5. Declaration regarding changes of premises Constitution, Technical staff etc. of the companies if applicable.6. Any other if necessary | 30 days | 1. Treasury Challan of licence fee of Rs.500+inspection fee of 200 ( Rs 700/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 250 per month or part thereof. |
| 38 | Application for grant/ renewal of a licence to manufacture for sale or distribution of homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensing holding licence in Form 25-C **Form 24C** and additional information. Renewal **Form 26-C.** | Renewal / return | 1. Condition of licence under Form 25C & schedule M-I of D&C Rules 1945 should be complied. 2. Photo copy of original/ renewal D/L with list of product all ready approved.3. Consolidated list of product.4. Production particulars for the last Licensing period.5. Declaration regarding changes of premises Constitution, Technical staff etc. of the companies if applicable.6. Any other if necessary  | 30 days | 1. Treasury Challan of licence fee of Rs.200+inspection fee of 100( Rs 300/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 100 per month or part thereof. |
| 39 | Application for grant/ renewal of a licence to manufacture for sale or distribution of drugs, specified in Schedule X and not specified in Schedule C and C(1) **Form 24F** and additional information. Renewal **Form 26-F.** | Renewal / return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 40 | Application for grant/ renewal of a licence to manufacture for sale or distribution of drugs, specified in Schedule C and C (1) excluding those specified in part XB and Schedule X **Form 27** and additional information. Renewal **Form 26**. | Renewal / return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 41 | Application for grant/ renewal of a loan licence to manufacture for sale or distribution of drugs, specified in Schedule C and C (1) excluding those specified in part XB and Schedule X **Form 27 A** and additional information. Renewal **Form 26-A**. | Renewal/ return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 42 | Application for grant/ renewal of a licence to manufacture for sale or distribution of drugs, specified in Schedules C and C (1) and X, **Form 27 B** and additional information. Renewal **Form 26-B.** | Renewal/return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 43 | Application for grant/renewal of license for the operation of Blood Bank for processing of whole blood and/ or preparation of blood components. **Form 27 C** and additional information. Renewal **Form 26-G.**  | Renewal/ return | 1. Plan layout of the premises
2. List of the machinery and equipment for collection, processing, storage and testing of whole human blood and its components.
3. Memorandum of association/ constitution of the firm
4. Copies of certificate relating to the educational qualification and experience of the competent technical staff.
5. Documents relating to ownership or tenancy of the premises.

**( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India))** | 90 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 44 | Application for grant/ renewal of a license to manufacture for sale or for distribution of large volume Parenteral/Sera and Vaccines excluding those specified in Schedule X **Form 27 D** and additional information. Renewal **Form 26-H.** | Renewal/ return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels. **( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India))** | 90 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 45 | Application for grant/ renewal of license to manufacture Blood products for sale or distribution **Form 27 E** and additional information. Renewal **Form 26-I.** | Renewal/return | 1. Plan layout of the premises
2. List of the machinery and equipment for collection, processing, storage and testing of whole human blood and its components.
3. Memorandum of association/ constitution of the firm
4. Copies of certificate relating to the educational qualification and experience of the competent technical staff.
5. Documents relating to ownership or tenancy of the premises.

**( Join Inspection carried out both CDSCO officers and State Drug Control Officers and License approved by the Drug Controller General (India))** | 90 days | 1. Treasury Challan of licence fee of Rs.6000+inspection fee of 1500( Rs 7500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.2. If the application is made within 6 months of its expiry after payment of an additional fees at the rate of Rs 1000 per month or part thereof. |
| 46 | Application for license to manufacture drugs for purpose of examination, test or analysis **Form 30** and additional information.  | Renewal/return | . Conditions of license Form 29 should be complied. | 30 days | Treasury Challan of licence fee of Rs 260/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 47 | Application for grant/ renewal of a license to manufacture cosmetics of sale or for distribution **Form 31** and additional information. Renewal **Form 33.** | Renewal/ return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | Treasury Challan of licence fee of Rs.2500+inspection fee of 1000 ( Rs 3500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 48 | Application for grant/ renewal of a loan license to manufacture cosmetics of sale or for distribution **Form 31A** and additional information. Renewal **From 33-A.** | Renewal/return | 1. Drug licence with list of products approved in the last licensing period.2. Consolidated list 3. Production particulars for the last Licensing Period.4. Declaration regarding the changes in the premises constitution (Directors/Partners), Technical Staff of the firm/Company.5. Original labels.  | 30 days | Treasury Challan of licence fee of Rs.2500+inspection fee of 1000 ( Rs 3500/-) under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
| 49 | Application for grant / renewal of approval for carrying out tests drugs/cosmetics or raw materials used in the manufacture of drugs specified in Schedule C & C1 thereof on behalf of licenses for manufacture for sale of drugs/cosmetics **Form 36** and additional information. Renewal **Form 38.** | Renewal/ return | 1. Photo copy of original/ renewal D/L.2. list of the products and raw materials tested during the license period3.List of the equipments4.Any other if necessary.  | 30 days | Treasury Challan of inspection fee of Rs 6015/- in case of testing of drugs specified schedule C & C1 and Rs 1500/- in case of testing of drugs specified other than schedule C & C1, homoeopathic drugs and cosmetics under the Head of Account “0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines. |
|  |  |  |  |  |  |